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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/578,096   | 12/22/2006  | Kai Zhang            | MNA-002             | 4758             |
| 31281 7590 01/27/2009<br>McLELAND PATENT LAW OFFICE, P.L.L.C.<br>11320 RANDOM HILLS ROAD<br>SUITE 250<br>FAIRFAX, VA 22030 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| SAIDHA, TEKCHAND   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1652   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/578,096

**Applicant(s)**

ZHANG, KAI

**Examiner**

Tekchand Saidha

**Art Unit**

1652

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-11 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### FINAL REJECTION

1. Amendment to claims and arguments filed 11/06/2008 is acknowledged. Claims 1, 3-11 & 13 are pending and under consideration in this examination.
2. Applicant's claim amendment and arguments filed 11/06/2008 have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s).
3. Any objection or rejection of record not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.
4. **New Matter added to claims only** - [New Matter rejection]

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), **at the time the application was filed**, had possession of the claimed invention. Applicant's addition [new matter] of the claims 13, is not supported by the original disclosure.

**Applicants are required to cancel the new matter in reply to this office action.**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13, lines 1-3 recites the phrase 'xanthophyll-rich photosynthetic microalga cell. The claims are indefinite because the metes and bounds encompassed by the

phrase are unclear, and the specification does not clarify the meaning. It is not clear how rich is 'xanthophyll-rich ...'. Clarification and/or appropriate amendment to the claim is requested. For examination purposes, therefore, a microalgal cell containing a reasonable level of xanthophyll in response to light would therefore be considered as 'xanthophyll-rich'.

6. Claims 1 & 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method for producing a xanthophyll from a photosynthetic microalga, comprising: a growth step wherein an encysted photosynthetic microalga containing xanthophyll is inoculated into a nutrient medium and grown; and an encystment step wherein the microalga obtained in the growth step is encysted.

The claim is very confusing because the steps are redundant and confusing in growing encysted photosynthetic microalga and then encysting them. Clarification is requested.

7. ***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 & 3-11 are rejected under 35 U.S.C. 103(a) as being obvious over Hata et al. [Journal of Applied Phycology (2001), 13(5), 395-402].

Claim 1 is drawn to a method for producing a xanthophyll from a photosynthetic microalga, comprising: a growth step wherein an encysted photosynthetic microalga containing xanthophyll is inoculated into a nutrient medium and grown; and an encystment step wherein the microalga obtained in the growth step is encysted; Claims 3-7 add limitation of carrying the growth and encystment steps being performed in a media and batch cultures and claims 9-11 add the limitation of the alga genus and species name and the xanthophyll to be astaxanthin.

Hata et al. teach a method for the Production of astaxanthin (a xanthophyll) by sequential heterotrophic- photoautotrophic cultivation of a green alga, *Haematococcus pluvialis*, a photosynthetic micro alga using a growth step in a nutrient medium and encystment step for encysting the micro alga. The method details cultivating of the cells heterotrophically to high cell concentration, followed by illumination (light irradiation) of the culture for astaxanthin accumulation. The optimum pH and temperature for heterotrophic biomass production were 8 and 25 °C, resp. A pH stat method was then used for fed-batch heterotrophic culture, using acetate as the organic carbon source. A cell concentration of 7 g L<sup>-1</sup> was obtained. Higher cell concentration could not be obtained because the cells changed from vegetative (zoospore, see page 395 column 2, line 9 and abstract) to cyst forms during the heterotrophic cultivation. However, by using repeated fed-batch processes, the cells could be maintained in the vegetative form, leading to more than two times increase in cell number output rate. When the

vegetative cells were transferred to photoautotrophic phase, there was a sharp decrease in the cell number and only very few cells encysted and accumulated astaxanthin. On the other hand, when the shift from heterotrophic to photoautotrophic condition was done when most of the cells had encysted, there was still a decrease in cell number but astaxanthin accumulation was very high. The astaxanthin concentration (114 mg L<sup>-1</sup>) and productivity (4.4 mg L<sup>-1</sup> d<sup>-1</sup>) obtained by this sequential heterotrophic-photoautotrophic cultivation method are very high compared to the data in the literature.

It would have been obvious for one of ordinary skill in the art to alternately use the encysted photosynthetic microalga as the starting material to grow followed by the encystment step. One of ordinary skill in the art would have been motivated to do so in view the above teaching, wherein "the vegetative cells when transferred to photoautotrophic phase, there was a sharp decrease in the cell number and only very few cells encysted and accumulated astaxanthin", leading one the alternate method of growing encysted cells and then encysting them, and doing so with a reasonable expectation of success. Barring any unexpected result, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, *prima facie* obvious.

Applicants' arguments pertain to the previous 102(b) rejection and are not relevant any more. The present rejection is under 35 U.S.C. 103(a)) since the claims have been amended.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Hata et al. Detailed teachings of Hata et al. are described above.

Claim 13 is drawn to a xanthophyll-rich photosynthetic microalga cell having a plurality of zoospores containing a xanthophyll, wherein the xanthophyll-rich microalga

cell is obtained by culture of an encysted microalga cell, and the xanthophyll content in the xanthophyll-rich microalgal cell is higher than the xanthophyll content of a microalga cell obtained by culture of a non-encysted microalga cell.

The photosynthetic micro alga having a zoospore (vegetative form) containing a xanthophyll, is considered merely a stage (encysted or non-encysted) in the micro algal growth cycle wherein the xanthophyll content may vary depending upon the stage of the cell, nutrient status or exposure to light, and wherein the encysted micro algae releases zoospores or microalgal cells obtained by culture and is no different than the zoospore stage taught by the reference. Without the explicit knowledge or exact content or extent of the richness of the xanthophyll content of the photosynthetic microalgal cell, the reference anticipates the claim.

9.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-11 & 13 are provisionally rejected under the judicially created doctrine of double patenting over claims 5-14 of copending Application No. 11/270,116

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

The claims in the copending application are drawn to species claims - directed to a method for producing astaxanthin, comprising: cultivating an encysted green alga in a nutrient medium while supplying carbon dioxide and providing irradiation with light at a photosynthetically active photon flux input of 8000 ~mol'photon/m<sup>3</sup>/s or more; extracting an oil component that contains astaxanthin; and recovering astaxanthin from the extracted oil component that 15 contains astaxanthin, as compared to the broad genus claims in the instant application. Since species claims anticipates genus claims, the instantly claimed genus claims are anticipated by the species claims of the copending application.

Applicants argue that since the copending application has not been examined yet, a terminal disclaimer will be filed in the copending application if such terminal disclaimer is found to be necessary during the prosecution of tile copending application. The rejection is therefore maintained until such a decision can be reached.

10. No claim is allowed.

**11. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.



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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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